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REMARKS

**The subject-matter of the claims in present application deals with surgical methods requiring a joining of hollow organs through anastomosis. Said surgical methods (i.e. the subject-matter) include:**

- (1) ~~The effects (or the results) to be attained by the method.~~
- (2) The surgical strategy – step by step – for attaining said results or effects.
- (3) The means deployed for attaining said results.

**The effects or results to be attained in applicant's case:**

- Realizing an annular joint (anastomosis) between two parts of hollow organs or segments of same hollow organ (either before or after excising a diseased portion of said hollow organ and either said excision is to be surgically carried out or not). Moreover, the annular joint needs to be realized at any anatomical location of said hollow organs to be joined.
- The type of joint to be realized is totally dependent on the surgeon's judgement and choice and his surgical strategy. He may choose one of the four types:
  - end to end,
  - end to side,
  - side to end, or a
  - side to side joint.

**The surgical strategy**

The surgical strategy represents the different surgical steps taken for achieving the desired results. They depend on:

- (a) The topographic location of the hollow organs to be operated, in a given human's anatomic environment. (This anatomic environment may be allegorically compared to a geographic ground surface in which topographic locations such as mountains, valleys and rivers may be obstacles to be surmounted). The digestive tube for instance isn't a simple hose with two open extremities. This tube is tortuous and has changing diameters all along of its course. It also has relative mobile portions whereas its other portions are sealed and fixed in curved positions to various degrees.

The oesophagus for example is covered with other anatomic structures and is totally sealed to the posterior body wall; The duodenum has a form of a C letter, and is also sealed and fixed to the posterior body wall, while being at the same time in continuity with a stomach (an enlarged pouch) having a relative mobility and with a small intestine of greater mobility etc...

Also, whereas the distal end of this digestive tube – i.e. the anus – is of relative ease for access to the surgeon and also of relative ease for a stapler introduction through due to the "elasticity" of its orifice, the proximal end of this tube – i.e. the oesophageal orifice – is much more difficult for surgical access and for stapler introduction. Indeed, this latter orifice is located in the mouth which is a square cavity into which emerge in different directions and in a curved manner other openings of other conducts (than the oesophagus). One of these other openings is the tracheo-bronchial orifice... Both – the tracheo-bronchial orifice and the

oesophageal orifices are covered here by more rigid structures and are consecutively inextensible.

For that reason, a stapler ~~even if flexible~~ has yet to have such technological features as to enable its introduction through these upper openings namely the upper oesophageal and tracheal orifices. (This will be explained in more detail hereinafter.). Also, the different steps taken in the surgical strategy must be adapted to the human's anatomic configuration of the hollow organs to be joined. It is clear –for instance- that a surgical strategy (such as in the prior arts to Bessler, Wilk and Kuramoto discussed hereinafter) exercised on the sigmoid colon which is of wide mobility, is easier than the same strategy exercised on the oesophagus-short of mobility and surrounded by the heart and the lungs-.

(b) The ambient conditions of work.

It is evident that the strategy needed to be used in order to achieve an expected result in open surgery conditions (in which abdomen or chest are "opened") is not the same as the one needed to be used in closed surgery conditions (in which those spaces are not "opened").

Indeed, whereas in conventional open-surgery, a relatively large incision is made in the abdominal or chest wall, enabling the hands of the surgeon to work with ancillary tools inside the abdomen or chest, closed-surgery is characterized by insertion of very thin specific tools through otherwise intact walls. This, within the aid of small tubular ports, which also serve to seal the very small openings during operation. These tools resemble long thin sticks on the head of which, there is an active part (like scissors, grasper, etc...). One of these tools –inserted like the others by transfixation of the abdominal or chest walls – contains optical means for viewing inside the abdominal or chest cavities and for realizing a surgical procedure via the other tools. (i.e. from the outside of the «closed» abdomen or thorax). It is also clear and easily comprehensible that tools intended for closed-surgery are not adapted and are completely impractical for open-surgery, and vice-versa tools for open-surgery cannot serve for closed-surgery. (Applicant's flexible stapler has unexpectedly been found usable in both open and closed surgery).

Closed surgery has also specific difficulties due to its specific conditions. In fact, surgical procedures requiring meticulousness like realizing a circular anastomosis by stitching are rendered practically close to impossible in these conditions and with huge risks of vital surgical complications.

From the above description it is easily understandable that a rigid stapler – for instance- cannot be used in those conditions.

The means deployed in present case:

Besides the surgeon and the basic closed surgery prior-art instrumentation, there is need for an annular stapler having specific technological characteristics adapted to the surgical strategy chosen for attaining the results specified in (1).

It is clear that any need for other obligatory equipment(s) [or any other obligatory device(s)] for realizing a specific surgical strategy, has costs and must be available in the operating room at the time the surgical strategy is taken

Moreover, the absence of said obligatory equipment, precludes that specific surgical strategy from being realized and necessitates the use of a different strategy (i.e. another series of surgical steps). That, of course, will consecutively urge the surgeon to modify and choose another result to expect instead of the initial one (for example: choosing a side-to-end anastomosis instead of an end-to-end initial choice).

In summary:

A surgical method should be analyzed (in terms of novelty and inventiveness) while comparing:

- 1) The results obtained by said methods while answering questions such as:
  - What type of anastomosis is obtained by the method described? End-to-End? End-to-Side? Side-to-End? Side-to-Side? More than one type? All types? If more than one, which other types? ...
  - Between which hollow organs the method described, can be realized? Has the method described any technical limits for being applied in other anatomic locations?
  - ...
- 2) The strategy of the method – detailed as a series/sequence of successive steps- should answer questions such as:
  - Is the train of steps in one method same or comparable (in view of its spirit) to another method?
  - Are the hollow organs to be joined through anastomosis in a comparable topographic human's anatomic environment?
  - Are we dealing with open or closed surgery? Both of them?
  - Has the method been described for other anatomic locations? Has it a possibility of being also applied in other anatomic locations than the one described? Which other anatomic locations?
  - ...
- 3) The means deployed for realizing the dealt surgical method, should answer questions such as:
  - Are the means required for realizing a given surgical method, same or comparable?
  - Does the surgeon need any other specific means (such as a guide wire, a separate endoscope...) for realizing the same surgical method besides the stapler?
  - ...

## FACTS

a) Present pending application – Toledano (Dtol)

The present claims before the Examiner are all directed toward methods for joining together two parts of different hollow organs or segments of same hollow organ through a stapled anastomosis, "at any anatomic location and in conjunction with any of a large variety of surgical procedures" (quoted from present specification page 12, lines 9-13), by the means of a flexible annular stapler to present applicant.

All varieties of joints (i.e. either end to end, end to side, side to end or side to side anastomoses) are concerned.

Also, these methods are subject to realization under open and/or more particularly under closed surgery conditions. (i.e. non invasive laparoscopic and/or thoracoscopic conditions).

Page 29 (lines 1-23) and page 30 (lines 1-18) in present specification give the common basis to the methods or surgical procedures described in the present claims. Each independent claim in present application, discloses a method for realizing any variety of circular anastomosis (i.e. end to end, end to side, side to end or side to side) by the means of a flexible annular stapler, in any chosen area predefined by a surgeon, between two different hollow organs or between segments of the same hollow organ. This joining may be applied to any of a number of hollow organs, including any part of the digestive tube and organs external thereto, such as the bronchial tree, the urinary bladder and urinary tree, gallbladder and biliary tree ... and not only to the colon. The illustrations of colon's surgical procedures in present specification are given just as examples. It is emphasized that neither of the parts to be joined need to be naturally tubular near the joint (like the cut end of the intestines), but may for example be a wall of the respective organ. What is common to all cases described in the claims of the present specification is that there is conceptually defined, for each of the two parts, a plane and an annular area thereon, the two annular areas being essentially congruent. During the joining operation, the two annular areas are brought together and conceptually combined into one annular area, over which the stapling and eventually the anastomosis take place. In the case that one of the parts is tubular at the joint, as in end-to-end or end-to-side anastomosis, (in which case that part is always cut across) the defined plane is transverse and at a short distance away from the plane of cutting. In the case that one of the parts presents an outer face of a wall at the joint, as in a side-to-end or side-to-side anastomosis, the plane is essentially at the face. Furthermore, in the case of a tubular part, there is an inherent opening through it at the defined plane and interior to the annular area (which opening is, in some procedures, not always initially accessible to the stapler, or, in some other procedures, may be intentionally closed off before the stapler reaches it). On the other hand, in the case of a part being joined at its wall, there is no such initial opening and, if required by a particular procedure (e.g. for insertion of part of the stapler thereto), a suitable opening has to be cut through the wall, interior to the annular area. Of course and as the *raison d'être*, after the end of the procedure there remains in all cases a clear opening through both parts.

Each independent claim in present application describes hence, a multitude of surgical situations finding expression in as much surgical procedures.

For example, Figures 11, 12 and 14 (as well as their appending explanations in the text of present specification), show how (at least) three different surgical procedures on a same and only hollow organ are described in a sole independent claim -such as claim 56. These same procedures (of claim 56) are moreover realizable either under open or under closed surgery as clearly showed in those figures and stated in page 24, lines 3-5 of present specification. Also, said same procedures are in all cases (such as in claim 56)- and as explained earlier- realizable on other hollow organs (i.e. other than the sigmoid colon examples of figures 11, 12 and 14).

Further, the methods described in the independent claims of present specification are not limited to any specific anatomic location. They can be realized anywhere between two tubular organs of the human body either under conditions of closed or of open surgery. Said methods can be realized, whether a resection of a diseased portion of a hollow organ is carried out or not, and whether said diseased portion obstructs the lumen of the hollow organ or not (i.e. the anastomosis joining can be realized either before or after said resection is carried out).

Furthermore, the means (i.e. the stapling device) used in all the methods described in present specification has technical features never disclosed in the prior art. One of these features is the interchangeability of positions of the head, anvil and even the knife with regard to a flexible

cable located in-between the anvil and the stapling part (along the longitudinal central axis of the device). While in prior art documents such as the French patent to present applicant (FR 9204490 cited in present disclosure), the anvil is necessarily attached to the tubular body and the head (containing the hammer, the stapling pins and the knife) is necessarily attached to the cable; in the present invention it is equally possible -as may be preferable in certain surgical procedures- for the anvil to be attached to the end of a flexible cable and for the head to be attached to the end of the tubular body. Moreover, the knife may be independently placed in either of two assemblies (i.e. four interchangeable alternatives). For this reason the two assemblies are referred to as jaws in the present application (See present application, page 13, line 19 – page 14, line 11).

In other prior art documents cited by the Examiner (Bessler-`508; Wilk-`486 an Kuramoto-`030 devices), the head (containing a hammer, stapling pins and a knife) is necessarily attached to the tubular body and the anvil is necessarily attached to a central axis rigid shaft. Finally, the prior-art in all, (including said French patent to present applicant) ignores totally the advantages of these different alternatives for several surgical strategies or procedures. Indeed and just as an example (relevant to an 18<sup>th</sup> embodiment to Kuramoto in D3 discussed hereinafter): In a surgical method/procedure necessitating the insertion of one jaw in oral way through the upper esophageal orifice, it may be preferable that the jaw to be inserted, be the anvil one (instead of the other jaw containing the hammer and stapling pins), since the anvil jaw is much less bulky (in its dimensions) than the other jaw. The easiness of insertion of said anvil jaw through the esophageal orifice, is furthermore facilitated by having a flexible cable in-between two spaced jaws, instead of a rigid shaft in-between them.

The following table 1 summarizes the surgical method disclosed in applicant's present claim 56 in regard to Dtol.

**Table I**

Expected result(s) of the method	End to end, End to side, Side to end and Side to side anastomoses
Main steps (strategy) of the method	<p>Closed surgery of all hollow organs at any anatomic location, whether a resection of organ is needed or not and whether before said resection is carried out or not before, through a train of steps that are <u>transposable to various surgeon's strategies on various hollow organs</u> in view of obtaining a predetermined one of the four types of anastomoses. These steps are:</p> <ul style="list-style-type: none"> <li>a) Using <u>laparoscopic and thoracoscopic</u> techniques and instrumentation and a flexible annular stapler having two interacting round jaws.</li> <li>b) Inserting in a <u>predetermined order</u> (according to the surgical needs), a first one followed by a second one said two interacting round jaws (wherein one of said jaws includes a stapling member and the other includes an anvil member) <u>through the mouth</u> of a patient.</li> <li>c) Depending on surgery needs, having either one of said jaws inside one hollow organ and the other jaw inside a second hollow organ to be joined.</li> <li>d) Closing by purse-string sutures or stapling the butts of the hollow organs by a linear stapler</li> <li>e) Operating said stapler</li> </ul>
Means deployed for realizing the method	A flexible annular stapler having two <u>interchangeable</u> round jaws

The following table II summarizes the surgical method disclosed in applicant's present claim 61 in regard to Dtol.

**Table II**

Expected result(s) of the method	<b>End to end, End to side, Side to end and Side to side anastomoses</b>
Main steps (strategy) of the method	<p><b>Closed surgery of <u>thorax and/or abdomen</u> for joining all hollow organs <u>at any anatomic location</u>, <u>whether a resection of organ is needed or not and whether before or not</u>, said resection is carried out through a train of steps that are <u>transposable to various surgeon's strategies on various hollow organs of thorax and/or abdomen</u> in view of obtaining a predetermined one of the four types of anastomoses. These steps are:</b></p> <ul style="list-style-type: none"> <li>a) <b>Using laparoscopic and thoracoscopic techniques and instrumentation and a flexible annular stapler having two interacting round jaws.</b></li> <li>b) <b>Inserting either one (depending on surgery needs) of the two jaws through a natural or an artificial opening, and the other jaw through the <u>thoracic or through the abdominal body wall</u>.</b></li> <li>c) <b>Having one of said jaws inside one hollow organ and the other jaw inside a second hollow organ to be joined.</b></li> <li>d) <b>Closing by purse-string sutures or stapling the butts of the hollow organs by a linear stapler</b></li> <li>e) <b>Operating said stapler</b></li> </ul>
Means deployed for realizing the method	<b>Flexible annular stapler to present applicant having <u>interchangeable</u> jaws and at least one <u>detachable</u> jaw (either one, depending on surgery needs).</b>

**b) Bessler's patent – US 5411508 (D1)**

Bessler discloses a flexible annular stapler with specific technical characteristics with the object of overcoming the limitations of the rigid annular stapler version in open surgery conditions (See chapter "Background of the invention" in D1).

Bessler et al. give in column 14 lines 3-46 an example of use of their stapler considered by the Examiner as a surgical method.

The following table III summarizes the (supposed) surgical "method" disclosed in Bessler's – D1.

**Table III**

Expected result(s) of the method	an <u>end-to-end</u> anastomosis between two unjoined sections of left colon.
Main steps (strategy) of the method	<p>a) Realizing a <u>large opening of the abdomen in open</u> surgical conditions, thus "<u>using different, invasive surgical tools</u>";</p> <p>b) Resecting a diseased colon portion by "<u>using different, invasive surgical tools, leaving two unjoined sections of tubular colon</u>"; (<i>terms quoted from Bessler</i>)</p> <p>c) Extracting manually the diseased colon portion <u>through the wide opening of the abdominal cavity</u>;</p> <p>d) Inserting by <u>transanal</u> way the Bessler's flexible annular stapler such that the <u>anvil is placed in the distal section</u> (as to the anus) of the resected colon and the <u>stapling head is placed in the proximal section</u> (as to the anus);</p> <p>e) Realizing (obligatorily) an <u>only partial closure</u> (around two para-central cables) of the open ends of the proximal and distal sections;</p> <p>f) Operating said Bessler's stapler.</p>
Means deployed for realizing the method	<p>A flexible annular stapler (to Bessler) having two <u>nondetachable and noninterchangeable round jaws</u> in which;</p> <ul style="list-style-type: none"> <li>- an <u>anvil jaw located on the apex</u> of the stapler is <u>attracted by two lateral cables</u> toward a stapling jaw (containing a hammer and stapling pins)</li> <li>- a <u>stapling jaw attached to a flexible tubular body</u> in which <u>hydraulic forces push</u> stapling pins toward the anvil jaw; and</li> <li>- a <u>central cylindrical rigid body (86) in-between the two jaws</u> for their axial alignment</li> </ul>

It is to be noted that with Bessler's stapler, the closure of the open ends to be joined must be a partial closure only, leading obligatorily to an only partially (and never totally) closed butt(s). The reasons for that -evoked by Bessler himself in Col. 14, lines 30-34 of D1- relies on the fact that when operating the stapler, the two paracentral cables (110) (around which a purse-string like suture takes place) have to be free in their axial movement and let (also) the rigid cylindrical aligning member (86) free in its axial movement. Also, in these conditions, the use of a linear stapler to "press" the tissue surrounding the opening to form a pair of adjoining lips together" is compromised. (A linear stapling will create a totally closed butt compromising said movement!) Bessler in D1 col. 14, lines 25-27 evokes "Instead of string-like sutures for



tying the colon ends, a flat stapling device may be used". In the context of present discussion, the applicant notes that it couldn't be found in whole D1 disclosure, to which kind of "flat" stapling devices, the author of D1 makes an allusion to. (it is just reminded that a clip applicator or a wound closure stapler are also flat stapling devices!)

Further, in one and only sentence in D1 disclosure, the laparoscopic (closed) surgery is roughly approached (tackled). The following is a quotation of that sentence:

*"By providing a gastrointestinal stapling device having a long flexible tube (on the order of about 90 cm) virtually all colon resections could be performed through the rectum and laparoscopically, with minimal invasive surgery. In addition to colon resection, the gastrointestinal stapler could allow laparoscopic esophageal, stomach, proximal and distal small bowel and possibly biliary anastomosis to be performed."*

It is clear that such sentence never shows neither discloses how, nor (moreover) describes any surgical method to use in closed laparoscopic conditions.

The applicant respectfully disagrees with the Examiner's statement, so as to consider that D1 "clearly discloses the (above described) "method" being performed laparoscopically or closed".

It is evident that it's not sufficient to claim that something can be done without doing or showing how to do it unless it's something evident. "Saying is one thing, doing another"! One could retort to obviousness under 35 USC § 103 (a). However, the above quotation of D1 (col. 15, lines 45-53) cannot be reasonably viewed as complying with that USC paragraph with which the Examiner is certainly acquainted. It is simply reminded that conditions of closed surgery in which the abdomen (or chest) spaces are closed, precluding surgeon's hands from working inside those spaces differs enormously from the conditions of open surgery, in which the abdomen (or chest) spaces are opened letting (allowing) the hands of the surgeon working in. Bessler et al. never disclose how to surmount and solve the problems encountered in closed surgery.

#### c) Wilk's patent - US 5330486 (D2)

Contrary to Bessler in D1, Wilk in D2 does disclose methods for joining hollow organs in laparoscopic conditions.

Wilk discloses in D2 several anastomosis forming means in laparoscopic conditions (entitled in his application "associated instruments"). These means comprise a linear anastomosis stapling device combined with an endoscope, a purse-string forming device, an endoscopic surgical assembly connected to an anastomosis forming device, an endoscopic surgical assembly comprising a flexible anastomosis forming device inserted through an expandable biopsy-type channel of a sheath which also encloses an endoscope, a magnetic anastomosis forming device, and more... Yet, it's surprising that the term "annular" or "circular" stapler is never mentioned in D2.

In USPTO Office Action mailed 13 March 2007, the Examiner has urged Figure 9 and accompanying description to Wilk (in D2) as anticipating applicant's claims.

**FIG. 9** in D2 represents (quoted from D2) - "*a schematic side elevational view of a resected bowel section, showing a step in the performance of an anastomosis in accordance with (D2) invention*". In that figure, a stapling device looking like a flexible annular stapler is shown

inside a tubular organ. However, the appending description to this figure specifies that the device concerned is a "flexible anastomosis-forming device 150" described in figure 7 ( and whose appending explanations, here again, do not specify as being an annular or circular stapler having two round jaws).

For the analysis to follow, let's consider the stapler of FIG. 9 to Wilk, as being "flexible annular stapler having two interacting and possibly invertible round jaws" such as in applicant's claim 56.

The following table IV summarizes, the surgical "method" described in relation with Fig. 9 in Wilk -D2.

**Table IV**

Expected result(s) of the method	an <u>end-to-end</u> anastomosis between two unjoined sections of colon.
Main steps (strategy) of the method	a) Using laparoscopic techniques and instrumentation b) Resecting a colon bowel section, leaving <u>two unjoined sections of tubular colon</u> ; c) Inserting by <u>transanal</u> way, the Wilk's flexible annular stapler such that the <u>anvil is placed in the distal section</u> (as to the anus) of the resected colon and the <u>stapling head is placed in the proximal section</u> (as to the anus); d) Closing by <u>purse-string sutures</u> around a <u>central rigid rod (172)</u> , the open ends of the proximal and distal sections; e) Operating said stapler
Means deployed for realizing the method	Annular flexible stapler (of Fig. 9 to Wilk) having two <u>nondetachable and noninterchangeable round jaws</u> in which; <ul style="list-style-type: none"> <li>- an <u>anvil jaw located on the apex</u> of the stapler is <u>attracted by</u> a rigid rod (172) toward a stapling jaw (containing a hammer and stapling pins)</li> <li>- a <u>stapling jaw attached to a flexible tubular body</u> in which stapling pins are <u>pushed</u> toward the anvil jaw; and</li> <li>- a <u>central rigid rod (172) in-between the two jaws</u>.</li> </ul>

It is emphasized that in the context of the hereabove method and stapler of Fig.9 to Wilk, a closure of butt ends of the hollow organs to be joined is neither described nor can be realized by a linear stapler. Indeed, in applicant's case, the flexible cable, owing to its thinness, does not materially interfere with that linear stapling operation and allows the joining of the lips around itself. (See Fig.17 and its appending text in Dtol). This technological feature doesn't exist at all in D2 to Wilk. Its equivalent in fig.9 to Wilk is a central rigid rod (172) in-between the jaws, precluding it from the tremendous advantage of its use in various surgical procedures in open and more particularly closed surgery.

c) Kuramoto's patent – US 5395030 (D3)

Kuramoto et al. disclose in D3 entitled "surgical device for stapling and fastening body tissues", at least twenty-two embodiments of stapling and tissue fastening devices. These devices include a large variety of staplers: either linear staplers forming straight parallel seams ("TA" type), linear stapler forming straight parallel seams with a linear knife between said parallel seams ("GIA" type), circular staplers, partially circular staplers, wound-closure stapler, clip applicators/endoscope, combined staplers with other means such as endoscopes, guide wires, forceps, and more and more ...

As in Bessler's case, Kuramoto et al. do not disclose surgical methods/strategy but give directions for use of said various embodiments protected by their patent for their technological aspects. As in Bessler's case, the Examiner has chosen to consider those directions for use as surgical methods.

Two of the embodiments disclosed in D3 –namely the 1<sup>st</sup> and the 18<sup>th</sup> -have been considered by the Examiner as pertinent toward present application.

The 1<sup>st</sup> embodiment in D3 is accompanied by drawings Figs. 1 to 4B.

Fig.3 and its accompanying text in D3 represents the supposed surgical method of the 1<sup>st</sup> embodiment objected by the Examiner.

The following table V summarizes, the surgical "method" described in relation with Fig. 3 in Kuramoto –D3.

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Table V

Expected result(s) of the method	an <u>end-to-end</u> anastomosis between two <u>unjoined sections of colon</u> .
Main steps (strategy) of the method	<p>a) Using either open (traditional) surgery or laparoscopic techniques and instrumentation;</p> <p>b) Excising a diseased colon portion, leaving <b>two unjoined sections of tubular colon</b>;</p> <p>c) Applying a tying thread (purse string suture) to each severed end of the colon;</p> <p>d) Inserting by <u>transanal</u> way, the Kuramoto's flexible annular stapler of 1<sup>st</sup> embodiment such that the <u>anvil is placed in the distal section</u> (as to the anus) of the resected colon and the <u>stapling head is placed in the proximal section</u> (as to the anus);</p> <p>e) Closing said purse-string sutures around a central rigid tubular shaft (23), the open ends of the proximal and distal sections;</p> <p>f) Operating said stapler.</p>
Means deployed for realizing the method	<p>Annular flexible stapler (of Fig. 1-3 to Kuramoto) having two <u>nondetachable and noninterchangeable round jaws</u> in which;</p> <ul style="list-style-type: none"> <li>- an <u>anvil jaw located on the apex of the stapler is attracted by a 1<sup>st</sup> moving means via a rigid rod (23) toward a stapling jaw (containing a hammer and stapling pins)</u></li> <li>- a <u>stapling jaw attached to a flexible tubular body in which stapling pins are pushed via a 2<sup>nd</sup> moving means (hydraulic) toward the anvil jaw; and</u></li> <li>- a <u>central rigid tubular shaft (23) in-between the two jaws.</u></li> </ul>

As in Wilk's case, the 1<sup>st</sup> embodiment to Kuramoto has a central rigid tubular shaft (23) in-between the jaws, precluding it from being usable for the linear stapling of the butt ends such as in applicant's case (Fig 17 in Dtol).

The 18<sup>th</sup> embodiment in D3 represents the second "supposed" surgical method objected by the Examiner as anticipating applicant's claims. It has for accompanying drawings in D3, the figures 51-53.

The following table VI summarizes, the surgical "method" described in relation with Fig. 51-53 in D3.

**Table VI**

Expected result(s) of the method	a <u>side-to-end anastomosis between the stomach and a severed portion of small intestine.</u>
Main steps (strategy) of the method	<ul style="list-style-type: none"> <li>a) Using either open (traditional) surgery or laparoscopic techniques and instrumentation;</li> <li>b) Inserting an anvil jaw including a <u>rigid connector (236)</u> into a severed end portion of the small intestine;</li> <li>c) Applying a tying thread (purse string suture) around said rigid connector;</li> <li>d) Forming an opening (241) in the wall of the stomach;</li> <li>e) Inserting through the mouth into the stomach, an endoscope containing a guide wire (234);</li> <li>f) Inspecting by the endoscope said stomach opening and advancing it through said opening such as to retrieve said connector (236) and to connect it to said guide wire (234);</li> <li>g) Pulling back the endoscope without mobilizing the guide wire connected to the anvil's connector;</li> <li>h) Threading the free end of said guide wire through the stapling jaw and through the insertion section of the 18<sup>th</sup> embodiment Kuramoto's flexible stapler;</li> <li>i) Pushing said stapler through the mouth into the stomach;</li> <li>j) Operating the stapler.</li> </ul>
Means deployed for realizing the method	<ul style="list-style-type: none"> <li>a) A flexible endoscope having a wire guide channel.</li> <li>b) A guide wire (234)</li> <li>c) An annular flexible stapler (of 18<sup>th</sup> embodiment to Kuramoto) having a <u>detached anvil jaw with non-interchangeable jaws</u> having: <ul style="list-style-type: none"> <li>- a <u>stapling jaw</u> (containing hammer and stapling pins) <u>obligatorily attached to a flexible tubular body</u> and</li> <li>- an <u>anvil jaw obligatorily located on the apex</u> of the stapler (<u>attracted by the guide wire(234) toward a stapling jaw</u>)</li> </ul> </li> </ul>

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**DISCUSSION****a) Office Action Summary**

- Claims 56-72 are pending in present application
- Claims 67-72 have been allowed and are deemed to be in order.
- Claims 58-60 have been rejected by the Examiner under 35 U.S.C, as being indefinite.
- Claims 56-57 have been rejected by the Examiner as being unpatentable over Bessler et al.— 5411508 in view of Kuramoto et al. — 5395030 under 35 U.S.C 103(a).
- Claims 56-57 have been rejected by the Examiner as being unpatentable over Wilk — 5330486 in view of Kuramoto et al. — 5395030 under 35 U.S.C 103(a).
- Claims 56-57 have been rejected by the Examiner as being unpatentable over Kuramoto et al. — 5395030 under 35 U.S.C 103(a).
- Claims 61-66 (strictly same to cancelled claims 44-49) have been allowed by the Examiner in previous USPTO Office Action mailed 18 August 2006 and are now (in present Office Action mailed 13 March 2007) rejected under 35 U.S.C 103(a) as being unpatentable over Kuramoto et al. — 5395030.
- Claim 64 has been rejected by the Examiner as being unpatentable over Kuramoto et al. — 5395030 in view of Bessler et al.— 5411508 under 35 U.S.C 103(a).

**b) Claim Rejection — 35USC §112**

The Examiner has rejected claims 58-60 as being indefinite and not complying with 35 USC 112, second paragraph ; since the term "superseded" in claim 58, is not understood. This claim (58) has been thus rewritten so as to eliminate the misunderstood term and to clarify the content of the claim. In so doing, claim 58 initially depending on claim 56, has been made now independent. Claims 59-60 haven't been changed and still remain depending on claim 58. Claims 58-60 introduce another novel and inventive feature (besides others) of the means used for realizing the method, namely a dilating balloon. This dilating balloon offers facilities in realization of the method described in these claims. Support for this feature and the facilities it offers can be found in the specification on page16, line24-page 17,line2; on page19,lines10-15; on Fig.5A; Figures 7 and 8. Claims 58-60 are consequently deemed to be now in order.

**c) §103(a) Rejections — Toledano (Dtol) versus Bessler US 5411508 (D1) in view of Kuramoto US 5395030 (D3)**

Independent claim 56 and its depending claim 57 are under this item. The rejection as to these claims under this item is respectfully traversed.

The Examiner has considered the above described method (in table III) to Bessler for colon resection, followed by an end-to end anastomosis, using Bessler's stapler via the anal opening as anticipating applicant's independent claim 56 (table I), since Kuramoto has described a method (another one summarized on table VI) in which he uses (his own) stapler inserted through the mouth. It would have been hence, obvious to realize said method (described in table III) to Bessler through the mouth too.

In other words, the Examiner considers that all the subject matter of applicant's claim 56 is already disclosed by D1 to Bessler except the insertion (of a flexible stapler) **through the mouth**; as if the insertion through the mouth was the one and only novel and inventive step in applicant's claim 56.

In light of the hereabove detailed explanations, it is clear that such interpretation is erroneous. In the discussion to follow, the non anticipation by D1 to Bessler will be respectfully traversed first and the "obviousness" secondly.

1°) Applicant's claim 56 - not anticipated by D1

As clearly explained earlier, independent claim 56 describes a *multitude* of surgical procedures at *various anatomic locations*, in which an anastomosis joint is required. In regard to that claim 56, at least three different surgical procedures are described for the only left colon location ( see Figures 11,12 and 14 of present application). The means by which said multitude of surgical procedures is carried out, is a flexible annular stapler having specific technological features disclosed by present applicant.

A simple comparison between table I (summarizing applicant's claim 56 while excluding the stapler's insertion through the mouth) and table III (summarizing D1's method) shows crucial differences between them. Neither the results are same nor the strategic steps of the method are same nor the means are same.

Table VII

	Bessler	Applicant's claim 56
Expected result(s) of the method	End to End anastomosis	Side to side, End to side, Side to end and End to end anastomoses
Main steps (strategy) of the method	<p>a) <u>Open surgery for colon after resection of a colon's segment.</u></p> <p>b) <u>One sole surgical strategy</u> (corresponding to one train of steps) in open surgery in view of obtaining an end to end anastomosis between two portions of colon</p> <p>c) <u>Transanal way of stapler's insertion</u></p>	<p>a) <u>Closed surgery of all hollow organs at any anatomic location, whether a resection of organ is needed or not and whether said joining is carried out before said resection or not.</u></p> <p>b) Series of steps that are transposable to various surgeon's strategies on various hollow organs in view of obtaining a predetermined one of the four types of anastomoses</p> <p>c) <u>Other ways of stapler's insertion (either natural or artificial openings)</u></p>
Means deployed for realizing the method	Annular flexible stapler (to Bessler) having two <u>non-interchangeable</u> round jaws	Annular flexible stapler having two <u>interchangeable</u> round jaws

2°) "Obviousness" rejections

It is first reminded that the basis for all obviousness rejections in UEC 103(a), can be raised "if the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matters pertains". Here again, the Examiner's argumentation is respectfully traversed. Indeed, we can easily observe through the following comparative table VIII (which summarizes tables III and VII) that we're dealing with completely different subject matters relying on different prior arts. Neither the results are same nor the steps of the method are same nor the means are same. Consecutively, we're out of the "obviousness" basis.

**Table VIII**

	Bessler	Kuramoto (18 <sup>th</sup> embodiment)
Expected result(s) of the method	End to End anastomosis	Side to End anastomosis
Main steps (strategy) of the method	- Open surgery for colon resection. - <u>steps completely different</u> from those of Kuramoto (compare tables III and VI)	- Closed surgery for joining stomach to intestine. - <u>steps completely different</u> from those of Bessler (compare tables III and VI)
Means deployed for realizing the method	Flexible annular stapler to Bessler	a) A flexible endoscope having a wire guide channel. b) A guide wire (234) c) An annular flexible stapler to Kuramoto (18 <sup>th</sup> embodiment)

It is interesting to remark that we would have been able to realize the Bessler's method with the Kuramoto's (18<sup>th</sup> embodiment) stapler and not the contrary. Nevertheless, it should also be noted that Kuramoto uses here three separate means (endoscope, guide wire and stapler) and not just one like Bessler!

**d) §103(a) Rejections – Toledano (Dtol) versus Wilk US 5330486 (D2) in view of Kuramoto US 5395030 (D3)**

Independent claim 56 and its depending claim 57 are under this item. The rejection as to these claims under this item is respectfully traversed.

The Examiner has considered the above described method (in table IV) to Wilk for colon resection, followed by an end-to end anastomosis, using the Wilk's "Fig.9 stapler" via the anal opening as anticipating applicant's independent claim 56 (table I), since Kuramoto has described a method (another one summarized on table VI) in which he uses (his own) stapler inserted through the mouth. It would have been hence, obvious to realize said method (described in table IV) to Wilk through the mouth too.

The same reasoning as for Bessler will be relevant here too. In other words, the Examiner considers that all the subject matter of applicant's claim 56 is already disclosed by D2 to Wilk except the insertion (of a flexible stapler) **through the mouth**; as if the insertion through the mouth was the one and only novel and inventive step in applicant's claim 56.

**1°) Applicant's claim 56 - not anticipated by D2**

A simple comparison between table I (summarizing applicant's claim 56 while excluding the stapler's insertion through the mouth) and table IV (summarizing D2 method) shows the



crucial differences between them. Neither the results are same nor the strategic steps of the method are same nor the means are same.

**Table IX**

	"Fig.9 stapler" to Wilk	Applicant's claim 56
Expected result(s) of the method	End to End anastomosis	Side to side, End to side, Side to end and End to end anastomoses
Main steps (strategy) of the method	a) Closed surgery for <u>colon after resection</u> of a colon's segment. b) <u>One sole surgical strategy</u> (corresponding to one train of steps) by closed surgery in view of obtaining an end to end anastomosis between two portions of <u>colon</u> after c) c) Closing <u>by purse-string sutures</u> around a central rigid rod (172), the open ends of the proximal and distal sections. d) <u>Transanal way</u> for stapler's insertion	a) Closed surgery of <u>all hollow organs at any anatomic location</u> , <i>whether a resection of organ is needed or not and whether the joining is carried out before said resection or not.</i> b) Series of steps that are transposable to <u>various surgeon's strategies on various hollow organs</u> in view of obtaining a <u>predetermined one of the four types of anastomoses</u> after c) c) Closing <u>by purse-string sutures or stapling butts by a linear stapler</u> d) <u>Other ways for stapler's insertion</u> (either through natural or through artificial openings)
Means deployed for realizing the method	Annular flexible stapler (Fig.9 of D2) having two <u>non-interchangeable</u> round jaws	Annular flexible stapler having two <u>interchangeable</u> round jaws

The steps of the "method" of Fig.9 (table IV) to Wilk, like its result (an end-to end anastomosis) can of course be realized through the means used by the applicant in claim 56. In other words, the surgical strategy described by Fig.9 to Wilk could have been included as a surgical strategy among a lot of other surgical strategies of applicant's claim 56. However, the means with which said surgical strategies are achieved in applicant's claim 56 are not the same. Moreover, applicant's claim 56, not only uses a different means for realizing its *various* surgical strategies than the one and only in Fig.9 to Wilk, but also has excluded the one to Wilk through the limitation of "stapler's insertion through the mouth". Consequently, to that unjustified limitation under the Examiner's instigation, other inventive possibilities have unhappily been lost from protection.

## 2°) "Obviousness" rejections

As in Bessler's case, we can easily observe through the following comparative table X (which summarizes tables IV and VII) that we're dealing with completely different subject matters

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relying on different prior arts. Neither the results are same nor the steps of the method are same nor the means are same. Consecutively, we're out of the scope of "obviousness" matter.

**Table X**

	Wilk (Fig.9)	Kuramoto (18 <sup>th</sup> embodiment)
Expected result(s) of the method	<b>End to End anastomosis</b>	<b>Side to End anastomosis</b>
Main steps (strategy) of the method	- Closed surgery for colon resection. - <u>steps completely different</u> from those of Kuramoto (compare tables IV and VI)	-Closed surgery for <b>joining stomach to intestine.</b> - <u>steps completely different</u> from those of Wilk (compare tables IV and VI)
Means deployed for realizing the method	<b>Flexible annular stapler of Fig.9 to Wilk</b>	a) <b>A flexible endoscope having a wire guide channel.</b> b) <b>A guide wire (234)</b> c) <b>An annular flexible stapler to Kuramoto (18<sup>th</sup> embodiment)</b>

As already said above, it is interesting to remark that we would have been able to realize the Wilk's method with the Kuramoto's (18<sup>th</sup> embodiment) stapler and not the contrary. Nevertheless, it should also be noted that Kuramoto uses here three separate means (endoscope, guide wire and stapler) and not just one like Wilk!

**e) §103(a) Rejections – Toledano (Dtol) versus Kuramoto US 5395030 (D3 – 1<sup>st</sup> embodiment) in view of Kuramoto US 5395030 (D3 – 18<sup>th</sup> embodiment)**

Independent claim 56 and its depending claim 57 are under this item. The rejection as to these claims under this item is respectfully traversed.

The Examiner has considered the method described by Kuramoto in Fig.3 (of D3) and summarized in tableV, for colon resection, followed by an end-to end anastomosis, using the stapler of Fig.3 (i.e. "1<sup>st</sup> embodiment") via the anal opening, as anticipating applicant's independent claim 56 (table I). Also, Kuramoto has described another method (summarized on table VI) in which he uses a stapler (18<sup>th</sup> embodiment) inserted through the mouth. To the Examiner's opinion, *"It would have been obvious to have inserted the embodiment of Fig.3 through the mouth in the event that the section of intestine to be removed is very near the stomach"* (quoted from the Examiner's Office Action).

In other words, the Examiner considers that all the subject matter of applicant's claim 56 is already disclosed by Fig.3 to Kuramoto except the insertion (of a flexible stapler) **through the mouth** as if the insertion through the mouth was the one and only inventive step in applicant's claim 56.

In light of the hereabove detailed explanations, it is clear that such interpretation is erroneous. In the discussion to follow, the non anticipation by Fig.3 embodiment to Kuramoto (in D3) will be respectfully traversed first and the "obviousness" secondly.

**1°) Applicant's claim 56 - not anticipated by Fig.3 embodiment (1<sup>st</sup> embodiment) to Kuramoto (D3)**

As clearly explained earlier, independent claim 56 describes a multitude of surgical procedures at various anatomic locations, in which an anastomosis joint is required. [These surgical procedures are certainly not limited to "the event that the section of intestine to be removed is very near the stomach" as claimed by the Examiner.] The means by which said multitude of surgical procedures is carried out, is a flexible annular stapler having specific technological features disclosed by present applicant.

A simple comparison between table I (summarizing applicant's claim 56 while excluding the stapler's insertion through the mouth) and table V (summarizing the method of Fig.3 in D3) shows crucial differences between them. Neither the results are same nor the strategic steps of the method are same nor the means are same.

Table XI

	1 <sup>st</sup> embodiment (Fig 3) of Kuramoto	Applicant's claim 56
Expected result(s) of the method	End to End anastomosis	Side to side, End to side, Side to end and End to end anastomoses
Main steps (strategy) of the method	<ul style="list-style-type: none"> <li>a) Closed surgery for <u>colon after resection</u> of a colon's segment.</li> <li>b) <u>One sole surgical strategy</u> (corresponding to one train of steps) in open surgery in view of obtaining an end to end anastomosis between two portions of colon</li> <li>c) Closing by <u>purse-string sutures</u> around a rigid tubular shaft (23), the open ends of the proximal and distal sections.</li> <li>d) Transanal way of stapler's insertion</li> </ul>	<ul style="list-style-type: none"> <li>a) Closed surgery of <u>all hollow organs at any anatomic location</u>, <i>whether a resection of organ is needed or not and whether before said resection is carried out or not.</i></li> <li>b) Series of steps that are transposable to <u>various surgeon's strategies</u> on various hollow organs in view of obtaining a predetermined one of the four types of anastomoses</li> <li>c) Closing by <u>purse-string sutures or stapling butts by a linear stapler</u></li> <li>d) Transanal and other ways of stapler's insertion (either natural or artificial openings)</li> </ul>
Means deployed for realizing the method	Annular flexible stapler of Fig.3 to Kuramoto, having two <u>non-interchangeable</u> round jaws	Annular flexible stapler having two <u>interchangeable</u> round jaws

## 2°) "Obviousness" rejections

As in Bessler's and Wilk's case, we can easily observe through the following comparative table XII (which summarizes tables V and VI) that we're dealing with completely different subject matters relying on different prior arts. Neither the results are same nor the steps of the

method are same nor the means are same. Consecutively, we're here again, out of scope of the "obviousness" matter.

**Table XII**

	Kuramoto ( 1 <sup>st</sup> embodiment)	Kuramoto (11 <sup>th</sup> embodiment)
Expected result(s) of the method	End to End anastomosis	Side to End anastomosis
Main steps (strategy) of the method	- Closed surgery for joining two segments of colon after resection. -Steps completely different from those of Kuramoto's 18 <sup>th</sup> embodiment (compare tables V and VI). -Transanal way of stapler's insertion	-Closed surgery for joining stomach to intestine. -Steps completely different from those of Kuramoto's 1 <sup>st</sup> embodiment (compare tables V and VI). -Insertion of stapler and allied means through the mouth
Means deployed for realizing the method	Flexible annular stapler of Fig.3 (1 <sup>st</sup> embodiment) to Kuramoto	a) A flexible endoscope having a wire guide channel. b) A guide wire (234) c) An annular flexible stapler to Kuramoto (18 <sup>th</sup> embodiment)

**f) §103(a) Rejections – Toledano (Dtol) versus Kuramoto's 18<sup>th</sup> embodiment US 5395030 (D3)**

Independent claim 61 and its depending claim 62-63 and 65-66 are under this item. The Examiner has rejected these claims under 35 USC as being unpatentable over Kuramoto's 18<sup>th</sup> embodiment in D3. The rejection as to these claims under this item is here again respectfully traversed.

A simple comparison between table II -summarizing the method of applicant's claim 61-with table VI that summarizes the method of Kuramoto's 18<sup>th</sup> embodiment, shows clearly huge differences between these two methods. Here again, neither the results are same nor the strategic steps of the method are same nor the means are same. The following comparative table XIII will summarize briefly the differences, showing consecutively the novelty and inventive steps made in applicant's claim 61 as to Kuramoto's 18<sup>th</sup> embodiment prior art.

**Table XIII**

	Toledano ( Dtol-Claim 61)	Kuramoto (D3-11 <sup>th</sup> embodiment)
Expected result(s) of the method	End to end, End to side, Side to end and Side to side anastomoses	Side to End anastomosis
Main steps (strategy) of the method	-Closed surgery of <u>thorax and/or abdomen</u> for joining all hollow organs at any anatomic location, <i>whether a resection of organ is needed</i>	-Closed surgery of <u>abdomen</u> for joining stomach to a resected intestine. -Steps completely different from those described by claim

	<p><i>or not and whether before said resection is carried out or not.</i></p> <p>-Method consisting on a series of steps that are transposable to various surgeon's strategies on various hollow organs of <u>thorax and/or abdomen</u> in view of obtaining a predetermined one of the four types of anastomoses.</p> <p>-Insertion of either one of the two jaws through an artificial or natural opening and the other jaw through the <u>thorax or</u> through the <u>abdomen</u>.</p>	<p><u>61 to Toledano (in Dtol) (See following explanations)</u></p> <p>–Obligatory insertion of stapling jaw and allied means through the mouth and obligatory insertion of anvil jaw stapler through the <u>abdominal wall</u></p>
Means deployed for realizing the method	Flexible annular stapler to present applicant having detachable and interchangeable jaws.	<p>Three separate means:</p> <p>a) A flexible endoscope having a wire guide channel.</p> <p>b) A guide wire (234)</p> <p>c) An annular flexible stapler to Kuramoto (18<sup>th</sup> embodiment)</p>

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It has already been explained that Kuramoto's "18<sup>th</sup> embodiment" method is very different in its steps from the one disclosed in applicant's claim 61. Applicant's method of claim 61 is detailed in Dtol on page 26, line 11- page 27, line 7 and illustrated schematically by Fig. 13 of same document. A simple observation of Fig. 13 in Dtol in comparison with Figs. 51-53 in D3 -illustrating Kuramoto's method- enables to realize that we're not dealing with the same matter at all. While Kuramoto's method requires insertion of separate endoscope and guide wire inside the stomach, present applicant's method in claim 61 does not use these separate means at all. While Kuramoto's method requires pulling out said endoscope and inserting a stapler having a wire guide channel, present applicant's method in claim 61 does not pull out any endoscope and does not have any wire guide channel in the stapler and so and so...

Independent claim 61 (and its depending claims 62-66), allowed by Office Action of August 18, 2006 and withdrawn from allowance by Office Action of March 13, 2007 is in view of the above discussion, novel and inventive and not anticipated by D3 to Kuramoto. The withdrawal of rejection as to these claims is respectfully requested.

**g) §103(a) Rejections – Toledano (Dtol) versus Kuramoto US 5395030 (D3) in view of Bessler US 5411508 (D1)**

Applicant's dependent claim 64 has been placed under this item by the Examiner. This claim has been rejected by the Examiner as being unpatentable over Kuramoto et al. – 5395030 (D3) in view of Bessler et al. – 5411508 (D1) under 35 U.S.C 103(a).

Claim 64 is depending on the above discussed inventive claim 61. It is therefore novel and inventive inasmuch it depends on novel and inventive claim 61.

h) Conclusions

In light of the above explanations and discussion, applicant submits that the base claims (56, 58 and 61) from which claims 57, 59-60, 62-66 depend are allowable, making claims 57, 59-60 and 62-66 allowable in their present form.

In view of expediting the examination's procedure, the applicant has chosen to amend the above discussed rejected claims, so as to sharpen and emphasize the crucial differences between said rejected claims and the prior art. Independent claims 56, 58 and 61 have been amended so as to emphasize that in each one of these claims, the surgical method described is realizable at any anatomic location and in conjunction with any of a large variety of surgical procedures. Support for that can be found in the application on page 12, lines 10-13. New depending claims 73-75 depending on claim 56 and new depending claim 76 depending on claim 58 were added in view of simplification and of a better protection of independent claims 56 and 58. Further, said independent claims 56 and 58 and also 61 have been amended as to also emphasize that in each of these claims, the surgical method is realized by the means of a flexible annular stapler having interchangeable jaws adaptable with various surgery's needs. Support for that can be found in the specification on page 13, line 19- page 14, line 11.

The amended independent claims now feature language which makes it absolutely clear that the surgical methods of the present invention are novel and inventive and not anticipated by any prior art.

Support for dependent claim 74 can be found in present specification on page 24, lines 17-22 and in Fig. 11<sup>(E)</sup> that shows a section of colon being removed either through the body wall or through the distal portion of colon.

In view of the discussion and corrections hereabove it is respectfully submitted that this application is now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted



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Haviv Toledano (Applicant/Inventor)

Date: June 05, 2007

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE CLAIMS**WHAT I CLAIM IS:**

Claim 56 (Currently amended): A method for joining two parts of hollow organs or segments of same hollow organ, at any anatomical location, over an annular area defined on a chosen plane in each of the two parts, whereby each part has an opening through the respective plane essentially inside the respective annular area ~~[under conditions of closed surgery, using laparoscopic or thoracoscopic techniques, performed on a patient];~~ said method being realizable in conjunction with any of a large variety of surgical procedures, whether resection of a hollow organ is to be carried out or not, and whether said resection is carried out before said joining or not; the method sequentially comprising the steps of-

- a) providing a flexible annular stapler ~~[having two]~~ comprising a first and a second interacting ~~[and possibly invertible]~~ round jaws; wherein one of said jaws includes at least a stapling member and the other jaw includes at least an anvil member;
- b) inserting in accordance with surgery facilities, in a predetermined order, said ~~[two interacting]~~ first and second jaws through the mouth of said patient into a first one of the two parts and advancing said jaws to where one jaw is inside the first part and the other jaw is inside the second one of the two parts, each jaw being substantially near the respective chosen plane for said joining;
- c) for each of the two parts, either shrinking the opening so as to form an at least partially closed butt that encloses the respective one of said jaws, or pressing the tissue surrounding the opening to form a pair of adjoining lips so as to enclose the respective one of said jaws and stapling said lips together by means of a linear stapler; and
- d) operating said annular stapler so as to pull the two said butts together and essentially combine the two annular areas into a combined annular area, to staple the two parts of hollow organs or segments to each other over said combined annular area and to cut away portions of said butts that are central to said combined annular area so as to realize either an end to end, end to side, side to end or side to side joint.

## Claim 57 (as originally filled)

Claim 58 (Currently amended): ~~[The method of claim 56, wherein the steps (a) to (d) are superseded by the following steps:]~~ A method for joining two parts of hollow organs or segments of same hollow organ at any anatomic location, over an annular area defined on a chosen plane in each of the two parts, whereby each part has an opening through the respective plane essentially inside the respective annular area, performed on a patient; said method being realizable in conjunction with any of a large variety of surgical procedures, whether resection of a hollow organ is to be carried out or not, and whether said resection is carried out before said joining or not; the method sequentially comprising at least the steps of-

- a) providing a flexible annular stapler comprising ~~[two]~~ a first and a second interacting round jaws wherein one of said jaws includes at least a stapling member and the other jaw includes at least an anvil member; ~~[and]~~ said stapler further comprising an inflatable balloon at [the] his top [of said stapler];
- b) inserting said balloon and said first and second jaws in a predetermined order in accordance with the surgery facilities, into a first one of the two parts while ~~[making use of]~~ using said inflatable balloon for dilating the path in said parts; advancing said jaws to where one jaw is inside the first part and the other jaw is inside the second one of the two parts, each jaw being substantially near the respective chosen plane for said joining;
- c) for each of the two parts, either shrinking the opening so as to form an at least partially closed butt that encloses the respective one of said jaws, or pressing the tissue surrounding the opening to form a pair of adjoining lips so as to enclose the respective one of said jaws and stapling said lips together by means of a linear stapler; and
- d) operating said annular stapler so as to pull the two said butts together and essentially combine the two annular areas into a combined annular area, to staple the two parts of hollow organs or segments to each other over said combined annular area and to cut away portions of said butts that are central to said combined annular area so as to realize either an end to end, end to side, side to end or side to side joint.

## Claims 59-60 (as originally filled)

Claim 61 (Currently amended): A method for joining two parts of hollow organs or segments of same hollow organ, at any anatomical location, over an annular area defined on a plane in each of said two organs or segments, under conditions of closed surgery using laparoscopic and/or thoracoscopic techniques, performed on a patient; the method being realizable in conjunction with any of a large variety of surgical procedures, whether a resection of a hollow organ is to be carried out or not, and whether said resection is carried out before said joining or not; the method comprising the steps of-

- (a) providing a flexible annular stapler having a flexible body, ~~two round jaws and~~ a flexible cable and two interacting jaws wherein one of said jaws includes at least a stapling member and the other of said jaws includes at least an anvil member; said flexible cable slidable through said body and through ~~a first~~ any chosen one of said jaws ~~and~~, having an end protrudable from said ~~first~~ chosen jaw defined hereafter as a first jaw; ~~said second~~ the other one of said jaws defined hereafter as a second jaw, being attachable to said end of said cable, said second jaw being initially detached;
- (b) inserting said first jaw into a first one of the two parts of hollow organs; advancing said first jaw to where it is inside the first part near the respective plane and causing said end of said cable to protrude from said first part;
- (c) introducing said second jaw into a closed thoracic or abdominal cavity through the patient's ~~body~~ thoracic or abdominal wall and attaching it in the inside of said closed cavity to said end of said cable;
- (d) having said second jaw inside the second one of the two parts of hollow organs and having each of the two parts form an at least partially closed butt at or near the respective plane, said butt enclosing the respective one of said jaws; and
- (f) operating said annular stapler so as to pull the two said butts together and essentially combine the two annular areas into a combined annular area, to staple the two parts of hollow organs or segments to each other over said combined annular area and to cut away portions of said butts that are central to said combined annular area so as to realize either an end to end, end to side, side to end or side to side joint.

Claims 62-72 (as originally filed)

Claim 73 (New): The method of claim 56, wherein any of steps (b) through (d) are carried out under conditions of closed surgery.

Claim 74 (New): The method of claim 73, wherein said insertion is effected through any natural opening of the patient's body and wherein the hollow organ resected portion, consecutive to said resection of a hollow organ, is removed either through a minimal invasive body wall incision of said patient, or through one of said two parts of hollow organs.

Claim 75 (New): The method of claim 56, wherein said insertion through the mouth is followed by insertion either through the esophageal opening or through the tracheo-bronchial opening.

Claim 76 (New): The method of claim 58, wherein any of steps (b) through (d) are carried out either under conditions of open traditional surgery or under conditions of closed surgery, using laparoscopic and/or thoracoscopic techniques.

  
Haviv Toledano (Applicant/Inventor)



**WHAT I CLAIM IS.**

Claim 56 (Currently amended): A method for joining two parts of hollow organs or segments of same hollow organ at any anatomic location, over an annular area defined on a chosen plane in each of the two parts, whereby each part has an opening through the respective plane essentially inside the respective annular area, performed on a patient; said method being realizable in conjunction with any of a large variety of surgical procedures, whether a resection of a hollow organ is to be carried out or not, and whether said resection is carried out before said joining or not; the method sequentially comprising at least the steps of-

- a) providing a flexible annular stapler comprising a first and a second interacting round jaws wherein one of said jaws includes at least a stapling member and the other jaw includes at least an anvil member;
- b) inserting in accordance with surgery facilities, in a predetermined order, said first and second jaws through the mouth of said patient into a first one of the two parts and advancing said jaws to where one jaw is inside the first part and the other jaw is inside the second one of the two parts, each jaw being substantially near the respective chosen plane for said joining;
- c) for each of the two parts, either shrinking the opening so as to form an at least partially closed butt that encloses the respective one of said jaws, or pressing the tissue surrounding the opening to form a pair of adjoining lips so as to enclose the respective one of said jaws and stapling said lips together by means of a linear stapler; and
- d) operating said annular stapler so as to pull the two said butts together and essentially combine the two annular areas into a combined annular area, to staple the two parts of hollow organs or segments to each other over said combined annular area and to cut away portions of said butts that are central to said combined annular area so as to realize either an end to end, end to side, side to end or side to side joint.

**Claim 57 (as originally filled)**

Claim 58 (Currently amended): A method for joining two parts of hollow organs or segments of same hollow organ at any anatomic location, over an annular area defined on a chosen plane in each of the two parts, whereby each part has an opening through the respective plane essentially inside the respective annular area, performed on a patient; said method being realizable in conjunction with any of a large variety of surgical procedures, whether a resection of a hollow organ is to be carried out or not, and whether said resection is carried out before said joining or not; the method sequentially comprising at least the steps of-

- a) providing a flexible annular stapler comprising a first and a second interacting round jaws wherein one of said jaws includes at least a stapling member and the other jaw includes at least an anvil member; said stapler further comprising an inflatable balloon at its top.
- b) inserting said balloon, and said first and second jaws in a predetermined order in accordance with the surgery facilities, into a first one of the two parts while using said inflatable balloon for dilating the path in said parts; advancing said jaws to where one jaw is inside the first part and the other jaw is inside the second one of the two parts, each jaw being substantially near the respective chosen plane for said joining;
- c) for each of the two parts, either shrinking the opening so as to form an at least partially closed butt that encloses the respective one of said jaws, or pressing the tissue surrounding the opening to form a pair of adjoining lips so as to enclose the respective one of said jaws and stapling said lips together by means of a linear stapler; and

Claim 76 (New): The method of claim 58, wherein any of steps (b) through (d) are carried out either under conditions of open traditional surgery or under conditions of closed surgery, using laparoscopic and/or thoracoscopic techniques.



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